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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,367

12/10/2007

Elan Ziv

34783

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67801

7590

06/21/2011

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EXAMINER

NELSON, KERI JESSICA

ART UNIT

PAPER NUMBER

3772

MAIL DATE

DELIVERY MODE

06/21/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,367	Applicant(s) ZIV, ELAN	
	Examiner KERI NELSON	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29,33,34 and 36-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-19,23-28,33,34,36,37 and 39-42 is/are rejected.
- 7) ☒ Claim(s) 1-11,20-22,29 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date: 2/14/2011; 2/15/2011 (2); 3/30/2011; 4/14/2011; 5/11/2011; 5/23/2011; 5/25/2011; and 6/13/2011.

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DETAILED ACTION

This Office action is in response to the amendments and request for continued examination filed March 28, 2011 for application 10/593,367. The information disclosure statements filed February 14, 2011, February 15, 2011, March 3, 2011, April 14, 2011, May 11, 2011, May 23, 2011, and May 25, 2011 have been considered by the examiner on June 10, 2011 and the information disclosure statement filed June 13, 2011 has been considered by the examiner on June 14, 2011. Claims 12 and 33 have been amended and claims 39-42 are newly presented; claims 1-29, 33, 34, and 36-42 are currently pending.

Information Disclosure Statement

1. The information disclosure statement filed March 30, 2011 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 28, 2011 has been entered.

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 12-14, 16-19, 23-25, 27, 28, and 39-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Zunker et al. (US Patent 6,676,594). Zunker discloses an apparatus (100) for treating pelvic organ prolapse comprising a disposable thin main body (102+110+120) adapted to provide pelvic organ support when inserted into a vagina; an anchoring body (144) that selectively rests within at least one deformable receiving site (146), which is a hole or indentation located on an inner circumference of the main body allowing the anchoring body to be attached to the main body when resting within the at least one receiving site and removed from the main body when detached from the at least one receiving site; a device displacer (140, 142) adapted to impart movement to the apparatus; and an applicator (insertion tool) adapted for insertion of the apparatus; wherein the main body is three-dimensional and therefore extends along three axes (x, y, and z) such that it is non-planar; and wherein the apparatus is adapted to be flexible in response to a force applied on the apparatus while in the vagina and during removal from the vagina such that the main body is deformable at at least three points thereon (Fig. 8; column 5, lines 32-54; column 6, lines 20-50; column 7, lines 23-26).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 15 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zunker as applied to claims 12 and 23 above, in view of Sheen (US Patent 2,580,133). Zunker each discloses the invention substantially as claimed, as described above, but fails to teach that the apparatus further comprises a soft external layer on at least a portion of the main body. Sheen discloses a pessary (P) comprising a main body (13) having a soft external layer (10) made of sponge rubber (Figs. 2-3; column 1, line 52 – column 2, line 18) capable of preventing necrosis. At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by Zunker to include a soft external sponge rubber layer as taught by Sheen in order to enable the apparatus to press firmly against the vaginal walls without causing discomfort.

7. Claims 33, 34, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zunker et al. (US Patent 6,676,594). Zunker discloses a method of treating pelvic organ prolapse comprising the steps of inserting into a vagina an apparatus comprising a first main body portion (102+110+120) and a second anchoring portion (144) for treating pelvic organ prolapse; positioning the apparatus within the vagina wherein the apparatus exhibits a non-planar configuration after insertion; anchoring the apparatus within the vagina using the second anchoring portion; removing the apparatus from the vagina by using a suitable insertion/removal tool to release the anchoring portion from a receiving site on the main body portion; and disposing of the apparatus; wherein removal is facilitated by a device displacer (140+142) adapted to impart movement to the apparatus (Fig. 8; column 6, lines 20-50; column 7, lines 23-26). Although the embodiment taught by Zunker shown in Figure 8 fails to expressly show that the first main body portion's profile is reduced, Zunker further teaches another embodiment of

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the apparatus shown in Figures 11 and 12 which comprises detents (444 & 446) which engage with flanges (502 & 504) on an insertion/removal tool (500) while reduce the profile of the main body portion for removal from the vagina (Figs. 11-12; column 7, lines 8-22). At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the apparatus of Figure 8 taught by Zunker to include detents on the legs (110 & 120) for cooperation with a suitable insertion/removal tool as shown in Figures 11 and 12 by Zunker for the purpose of reducing the profile of the main body portion for easier removal from the vagina.

Allowable Subject Matter

8. Claims 1-11, 20-22, 29, and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments filed March 28, 2011 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI NELSON whose telephone number is (571)270-3821. The examiner can normally be reached on Monday - Thursday, 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJN
/KERI J. NELSON/
Examiner, Art Unit 3772
6/15/2011

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772